DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/11/2008 has been entered.

2. Currently Claims 1-6, 8-14, and 16-23 are pending. Claims 7, 15, and 24 have been cancelled.

3. Rejections for Claims 1-6, 8-14, and 16-23 have been made below with response to arguments following.

Withdrawn Rejections

4. The rejection of the claims under 35 USC 112/First paragraph New Matter made in section 7 of the previous office action is moot based upon amendments to the claims.

Claim Objections

5. Claims 19 and 23 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

in proper dependent form, or rewrite the claim(s) in independent form. In the instant claims, Claim 6 and Claim 14 are already limited to an isotope.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite over the "component is a nutrient". Claim 6 defines the component as an isotope and therefore it is unclear if the component is a nutrient or an isotope.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. The following rejections are reiterations of the rejection set forth in the previous office action (5/11/2007). Response to Arguments follows.

9. Claims 1-6, 8-14, 16-19, and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Lytle et al. (Journal of Microbiological Methods Vol. 44 2001 p. 271) in view of Banning et al. (Microbiology 2003 Vol. 149 p. 47) as evidenced by dictionary.com (www.dictionary.com).

With regard to Claims 1 and 9, Lytel et al. teaches adhesion deficient gram-negative colonies were grown in a nitriloacetic acid-free basal salt medium with ^{13}C isotope as the sole carbon source (p. 273 1st column 1st paragraph). Lytel et al. teaches the cells were grown in a sealed tube (solid support) (p. 273 1st column 1st paragraph). Lytel et al. teaches the cells were grown for 20 minutes; therefore the growth of the bacteria would have created a film of colonies on the solid support (p. 273 1st column 1st paragraph). Lytel et al. teaches detecting of palmitic acid and oleic acid (fatty acids) (biomarkers) (Abstract). Lytel et al. teaches that this detection method can be used to

correlate biomarkers (palmitic acid and oleic acid) to in situ bioremediation or subsurface sediments (component of bioremediation pathway) (Abstract). Though Lytel et al. does not specifically teaches that the solid support is sterile, it is obvious that the method of Lytel et al. would use a sterile solid support. Lytel et al. teaches that all glassware was rinsed and heated to remove contamination (p. 270 1st column Materials), however, Lytle et al. does not specifically teaches that the stainless-steel tubing (solid support) was heated to sterilize. It is prima facie obvious to one of skill in the art, however, to sterilize components in which bacteria is grown in order to ensure that containments of the components are not grown instead of the bacteria of study. The skilled artisan would be motivated to sterilize all equipment before an experiment including the solid support in order to ensure that the experiment was detecting the bacteria of interest and to reduce the background containments. Lytel et al. teaches using ^{13}C labeled bacteria (Abstract).

With regard to Claim 2-3 and 10-11, Lytel et al. teaches detection of phospholipids fatty acids (Table 1 p. 274).

With regard to Claims 4-5 and 12-13, Lytel et al. teaches specific fatty acids can be used to trace bacteria (subset of microbial organism) (Abstract and p. 271 1st paragraph).

With regard to Claims 6, 14, 19 and 23, Lytel et al. teaches using ^{13}C labeled bacteria (Abstract).

With regard to Claim 8 and 16, Lytel et al. teaches performing PLFA analysis (p. 276 Results 3.2 Detection of unique negative ion of PLFA).

However, Lytel et al. does not teach contacting a microbial community at a subsurface site or down-well groundwater site.

With regard to Claims 1, 9, 17-18, and 21-22, Banning et al. teaches making biofilms from groundwater sites to detect bacteria in drinking water (abstract). It is noted that dictionary.com defines ground water as "the water beneath the surface of the ground, consisting largely of surface water that has seeped down; water beneath the earth's surface, often between saturated soil and rock, that supplies wells and springs", therefore the term groundwater includes a type of subsurface site.

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to modify the method of determine if active bioremediation activity is occurring as taught by Lytel et al. by using a microbial community at a groundwater site as taught by Banning et al. The ordinary artisan would be motivated to modify the method of Lytel et al. to use a microbial community at a groundwater site as taught by Banning et al. because Banning et al. teaches that groundwater provides a reservoir for pathogenic bacteria observed in drinking water distribution systems (abstract). Banning et al. teaches that the detection of the microbial in a biofilm can make determinations on the potential public health risk of water samples (p. 48 1st column 2nd paragraph).

Response to Arguments

The reply traverses the rejection. A summary of the arguments set forth in the reply is presented below with a response to arguments following.

The reply asserts that adhesion deficient gram negative bacteria as taught by Lytle et al. would not be able to establish a biofilm on a solid support as they would not be able to adhere to the support (p. 9 last paragraph).

This argument has been thoroughly reviewed but has not been found persuasive.

Applicant is arguing that the adhesion deficient bacteria will not form a biofilm on a solid support. However, it is noted that arguments of counsel cannot take the place of evidence of the record.

> The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a *prima facie* case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

This should not be construed as an invitation for providing evidence. As further stated in the MPEP 716.01 regarding the timely submission of evidence:

A) Timeliness.
Evidence traversing rejections must be timely or seasonably filed to be entered and entitled to consideration. In re Rothermel, 276 F.2d 393, 125 USPQ 328 (CCPA 1960). Affidavits and declarations submitted under 37 CFR 1.132 and other evidence traversing rejections are considered timely if submitted:
(1) prior to a final rejection,
(2) before appeal in an application not having a final rejection, or
(3) after final rejection and submitted
(i) with a first reply after final rejection for the purpose of overcoming a new

ground of rejection or requirement made in the final rejection, or
(ii) with a satisfactory showing under 37 CFR 1.116(b) or 37 CFR 1.195, or
(iii) under 37 CFR 1.129(a).

However, with regard to applicant's arguments that adhesion deficient colonies cannot be grown on a solid support, the state of the art at the time of filing indicates that such bacteria can be grown on a solid support. Johnson et al. (Applied and Environmental Microbiology October 2001 p. 4908) teaches the same adhesion deficient gram negative colonies as taught by Lytel et al. (DA001) were grown on acetate (solid support) (p. 4908 2nd column 1st paragraph). Therefore the art indicates that biofilms of these bacteria can be grown.

10. Claims 1-6, 9-14, 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elasri et al. (Applied and environmental microbiology May 1999 p. 2025) in view of Banning et al. (Microbiology 2003 Vol. 149 p. 47) as evidenced by dictionary.com (www.dictionary.com).

Elasri et al. teaches the response of a *P. aeruginosa* biofilm to stress by using a bioluminescent biosensor that responds to DNA damage (p. 2025 2nd column 2nd paragraph last sentence). With regard to Claim 1 and 9, Elasri et al. teaches P. aerugionsa (microbial flora) cell suspension was covered with strontium chloride solution to form small beads and placed on an electrophoresis tray (solid support) (p. 2025 Materials and methods 1st paragraph and last paragraph). Elasri et al. teaches incubating at room temperature (p. 2025 last paragraph). Elasri et al. teaches measuring the cell count after UV exposure (p. 2026 1st column 1st full paragraph).

Elasri et al. teaches correlating the response of *P. aeruginosa* to UV stress (Abstract). Though Elasri et al. does not specifically teach that the solid support is sterile, it is obvious that the method of Elasri et al. would use a sterile solid support. It is prima facie obvious to one of skill in the art, however, to sterilize components in which bacteria is grown in order to ensure that containments of the components are not grown instead of the bacteria of study. The skilled artisan would be motivated to sterilize all equipment before an experiment including the solid support in order to ensure that the experiment was detecting the bacteria of interest and to reduce the background containments. Elasri et al. teaches using strontium, which is listed in Table 1 of the instant application (p. 2025 Materials and methods last paragraph).

With regard to Claims 2-3 and 10-11, Elasri et al. teaches a method using a plasmid contains a fusion of the recA promoter of *P. aerugionsa* to the luxCDABE operon of *V. fischeri* (p. 2025 2nd column Bacterial Strain). Elasri et al. teaches that this plasmid contains the lux operon, which reduces flavin mononucleotide and a long fatty acid aldehyde in the presence of oxygen to emit light (p. 2025 1st column last paragraph). Elasri et al. teaches the reductase complex recycles the fatty acid allowing autonomous bioluminescence (p. 2025 1st column last paragraph). Therefore, the method of Elasri et al. teaches detection of light from the recycling of fatty acid. The fatty acid can therefore be considered the biomarker which is detected. Claims 4-5 and 12-13, the biomarker (the promoter of P. aerugionsa) is characteristic of a bacterial population (subset of microbial organisms).

With regard to Claim 6, 14, 19, and 23, Elasri et al. teaches using strontium, which is listed in Table 1 of the instant application (p. 2025 Materials and methods last paragraph).

With regard to Claims 20, Elasri et al. teaches adding alginate to the culture (biofilm) to test if alginate is a nutrient (p. 2027 1st column 1st full paragraph). Elasri et al. teaches using beads of strontium alginate matrix and measuring the nutrient level (alginate level) to determine response to UV C stress (p. 2027 2nd column 1st two full paragraphs).

With regard to Claim 7 and 15, Elasri et al. teaches using a clinical strain of *P. aeruginosa* (p. 2025 2nd column Materials and methods 1st paragraph).

However, Lytel et al. does not teach contacting a microbial community at a subsurface site or down-well groundwater site.

With regard to Claims 1, 9, 17-18, and 21-22, Banning et al. teaches making biofilms from groundwater sites to detect bacteria in drinking water (abstract). It is noted that dictionary.com defines ground water as “the water beneath the surface of the ground, consisting largely of surface water that has seeped down; water beneath the earth’s surface, often between saturated soil and rock, that supplies wells and springs”, therefore the term groundwater includes a type of subsurface site.

Therefore, it would have been prima facie obvious to one of skill in the art at the time of the invention to modify the method of determine if active bioremediation activity is occurring as taught by Elasri et al. by using a microbial community at a groundwater site as taught by Banning et al. The ordinary artisan would be motivated to modify the

method of Elasri et al. to use a microbial community at a groundwater site as taught by Banning et al. because Banning et al. teaches that groundwater provides a reservoir for pathogenic bacteria observed in drinking water distribution systems (abstract). Banning et al. teaches that the detection of the microbial in a biofilm can make determinations on the potential public health risk of water samples (p. 48 1st column 2nd paragraph).

Response to Arguments

The reply traverses the rejection. A summary of the arguments set forth in the reply is presented below with a response to arguments following.

The reply asserts Elasri et al. fails to teach the identifying biomarkers obtained from the microbes on said solid support into which isotopes from said substrate have been incorporated and identifying g the microbes present by analyzing the biomarkers and associating isotope containing biomarkers with particular microbes or subsets of microbial organisms (p. 10 last paragraph).

This argument has been fully reviewed but has not been found persuasive.

Elasri et al. teaches P. aerugionsa (microbial flora) cell suspension was covered with strontium chloride solution to form small beads and placed on an electrophoresis tray (solid support) (p. 2025 Materials and methods 1st paragraph and last paragraph). Therefore Elasri et al. teaches microbes on a solid support into which isotopes have been incorporated.

Elasri et al. teaches correlating the response of *P. aeruginosa* to UV stress (Abstract). Therefore Elasri et al. teaches analyzing the biomarkers (UV stress) to

correlate them to a particular subset of P. aeruginosa. Therefore all the limitations of the instant claims are taught.

Conclusion

11. No Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine Salmon/
Examiner, Art Unit 1634

/Carla Myers/
Primary Examiner, Art Unit 1634